



**3510-16-P**

**DEPARTMENT OF COMMERCE**

**United States Patent and Trademark Office**

**Deposit of Biological Materials**

**ACTION:** Notice of renewal of information collection; request for comment.

**SUMMARY:** The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the extension of an existing information collection: 0651–0022 (Deposit of Biological Materials).

**DATES:** Written comments must be submitted on or before [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments by any of the following methods:

- *Email:* [InformationCollection@uspto.gov](mailto:InformationCollection@uspto.gov). Include “0651–0022 comment” in the subject line of the message.
- *Federal Rulemaking Portal:* <http://www.regulations.gov>.
- *Mail:* Marcie Lovett, Records and Information Governance Branch, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–7728; or by email to [Raul.Tamayo@uspto.gov](mailto:Raul.Tamayo@uspto.gov) with “0651–0022 comment” in the subject line. Additional

information about this collection is also available at <http://www.reginfo.gov> under “Information Collection Review.”

## **SUPPLEMENTARY INFORMATION:**

### **I. Abstract**

This collection covers information from patent applicants who seek to deposit biological materials as part of a patent application. The information collected from such patent applicants consists of information and documentation demonstrating the applicant’s compliance with regulatory requirements, as well as information regarding the biological sample after it is deposited. This collection also covers applications from institutions that wish to be recognized by the USPTO as a suitable depository to receive deposits for patent purposes. The information collection requirements for these actions are separate, as further discussed below.

#### **A. Deposits of Biological Materials**

The deposit of biological materials as part of a patent application is authorized by 35 U.S.C. 2(b)(2). The term “biological material” is defined in 37 CFR 1.801 as including material that is capable of self-replication, either directly or indirectly. When an invention involves a biological material, sometimes words and figures are not sufficient to satisfy the statutory requirement for patentability under 35 U.S.C. 112 (every patent must contain a description of the invention sufficient to enable a person (knowledgeable in the relevant science), to make and use the invention as specified by 35 U.S.C. 112). In such cases, the required biological material must either be:

(1) known and readily available (neither condition alone is sufficient) or (2) deposited in a suitable depository that has been recognized as an International Depositary Authority

(IDA) established under the Budapest Treaty, or a depository recognized by the USPTO to meet the requirements of 35 U.S.C. 112. Under the authority of 35 U.S.C. § 2(b)(2), the deposit rules (37 CFR 1.801–1.809) set forth examining procedures and conditions of deposit which must be satisfied in the event a deposit is required. The rules do not address the substantive issue of whether a deposit is required under any particular set of facts.

In cases where a deposit is necessary, the USPTO collects information to determine whether the depositor is in compliance with the deposit rules. This includes statements proving notification to the interested public on where to obtain samples of the deposits and confirming that all restriction on access to the deposit will be irrevocably removed upon issuance of the patent. A viability statement also must be submitted to the USPTO showing that the biological material was tested by the depository or another, the conditions of the test, and that it is a viable or acceptable deposit. A viability statement is not required when a deposit is made and accepted under the Budapest Treaty.

This collection also covers additional information that may be gathered by the USPTO after a biological material is deposited into the recognized depository. For example, depositors may be required to submit verification statements for biological materials deposited after the effective filing date of a patent application or written notification that an acceptable deposit will be made. Occasionally a deposit may be lost, contaminated, or otherwise is not able to self-replicate, and a replacement or supplemental deposit needs to be made. In that event, this collection covers the requirement that the depositor submit a written notification to the USPTO concerning

the particulars of the situation and request a certificate of correction by the USPTO authorizing the replacement or supplemental deposit.

There are no forms associated with the information collected by the USPTO in connection with the deposit of biological materials.

## **B. Depositories**

Institutions that wish to be recognized by the USPTO as a suitable depository to receive deposits for patent purposes, are required by 37 CFR 1.803 to make a request demonstrating that they are qualified to store and test the biological materials submitted to them under patent applications. This collection covers the information gathered in the request to allow the USPTO to evaluate whether such an institution has demonstrated that its internal practices (both technical and administrative) and the technical ability of the staff and the facility are sufficient to protect the integrity of the biological materials being stored. For example, this collection covers documentation from depositories that verifies that their practices and procedures, the technical competence of their staff, and their facilities fulfill the stringent requirements spelled out under the rules.

This collection also covers additional information gathered by the USPTO that may be needed after a depository has been recognized by the USPTO. For example, this collection covers requests to handle additional types of biological materials other than the material originally recognized, and viability statements that depositories may submit (on behalf of depositors) for deposits tested at the depository and/or documentation proving the public has been notified about where to obtain samples.

There is no application form associated with requests to become a recognized depository.

## **II. Method of Collection**

By mail, hand delivery, or electronically to the USPTO.

## **III. Data**

*OMB Number:* 0651–0022.

*Form Number(s):* None.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Businesses or other for-profits; and not-for-profit institutions.

*Estimated Number of Respondents:* 951 responses per year. The USPTO estimates that approximately 3% (28) of these responses will be from small entities.

*Estimated Time Per Response:* The USPTO estimates that it will take the public 1 hour to gather the necessary information, prepare the appropriate form or documents, and submit the information to the USPTO for a deposit of biological materials. The USPTO estimates that it will take the average depository seeking approval to store biological materials approximately 5 hours to collect and submit the necessary approval information.

*Estimated Total Annual Respondent Burden Hours:* 955 hours.

*Estimated Total Annual Respondent Cost Burden:* \$33,021. The USPTO estimates a professional hourly rate of \$34.40 for a senior administrative assistant (BLS rate; 43-1011 First Line Supervisors of Office and Administrative Support Workers) to collect and submit the deposit information. The USPTO expects that the average depository seeking approval to store biological material will be prepared by attorneys at an

estimated rate of \$68.22 (BLS rate; 23-1011 Lawyers) per hour. Therefore, the USPTO estimates that the respondent cost burden for this collection will be approximately \$33,021 per year.

#	Item	Estimated Time for Response (Hours) (a)	Estimated Annual Responses (b)	Estimated Annual Burden Hours (a) x (b) / 60 = (c)	Rate (\$/hr) d	Total Costs (c) x (d) = (hourly cost burden)
1	Deposited Materials	1 hour	950	950	\$34.40	\$32,680
2	Depository Approval	5 hours	1	5	\$68.22	\$341
<b>Total</b>		---	<b>951</b>	<b>955</b>	---	<b>\$33,021</b>

*Estimated Total Annual Non-hour Respondent Cost Burden:* \$2,823,236. There are no maintenance costs, recordkeeping costs, or filing fees associated with this information collection. However, this collection has annual (non-hour) costs in the form of capital start-up and postage costs.

Depositories charge fees to depositors; all depositories charge about the same rates for their services. For example, the American Type Culture Collection (ATCC), one of the world's leading biological supply houses and recognized patent depositories, offers comprehensive patent services for \$2,500 per deposit. Most deposits received from outside the United States require an import permit from the U.S. Department of Agriculture (USDA) as well as a Public Health Service (PHS) permit, available from the Centers for Disease Control and Prevention (CDC), for importation of agents infectious to humans. There is no extra charge for this permit application processing. The USPTO estimates that the total non-hour respondent cost burden in the form of capital start-up costs amounts to \$2,375,000.

In addition, this collection has postage costs. Biological deposits are generally shipped to the depository “Domestic Overnight” by Federal Express (FedEx) and, since depositors are urged to supply frozen or freeze-dried material, it must be packed in dry ice according to a representative from the Patent Department at ATCC. Dry ice itself is considered a dangerous good and requires special packaging. Additional FedEx special handling charges for inaccessible dangerous goods shipments of \$40 per shipment apply for temperature-sensitive biological materials and also for the dry ice. An average cost for shipping by FedEx “Domestic Overnight” is estimated to be \$75. If the shipment requires pick-up by FedEx, there is an additional charge of \$4. Special packaging is also required for these shipments. According to DG Supplies Inc., a supplier of infectious and diagnostic goods packaging, the average cost of frozen infectious shippers is estimated to be \$352.82 per package for specimen shipments requiring refrigeration or dry ice. Therefore, postage costs average \$471.82 per shipment. The postage cost for a depository seeking recognition is estimated to be \$7.65, sent to the USPTO by USPS Priority Mail legal flat rate envelope.

The USPTO estimates that the (non-hour) respondent cost burden in the form of mailing costs amounts to \$448,236.

Item #	Item/Type of Cost	Estimated Annual Responses	Amount	Totals
	Deposit Costs			
1	Deposited Materials	950	\$2,500.00	\$2,375,000.00
	<b>Total Fees</b>			<b>\$2,375,000.00</b>
	PACKAGING/POSTAGE COSTS			

Item #	Item/Type of Cost	Estimated Annual Responses	Amount	Totals
1	Deposited Materials – Mailing Costs	950	\$119.00	\$113,050.00
1	Deposited Materials – Packaging Supplies	950	\$352.82	\$335,179.00
2	Request for Depository Approval	1	\$7.65	\$7.65
	<b>Total Postage/Packaging</b>			<b>\$448,236.65</b>
	<b>Total Annual (Non-Hour) Cost Burden</b>			<b>\$2,823,236.65</b>

Therefore, the USPTO estimates that the total (non-hour) respondent cost burden for this collection in the form of capital start-up costs and postage costs is \$2,823,236.

#### **IV. Request for Comments**

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

USPTO invites public comments on:

- (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (d) Ways to minimize the burden of the collection of information on respondents, e.g.,

including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

**Marcie Lovett,**

*Records and Information Governance Branch,*

*Office of the Chief Administrative Officer, USPTO*

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